

Multicomponent Behavioral Sleep Intervention for Insomnia in Older Adults with Mild Cognitive  
Impairment

Informed Consent

IRB Protocol Number: 832826

Approval Date: 04/03/2019



**Institutional Review Board**

3800 Spruce St., First Floor Suite 151  
Philadelphia, PA 19104  
Phone: 215-573-2540  
(Federalwide Assurance # 00004028)

DATE: 03-Apr-2019  
TO: Miranda S Varrasse  
CC:

RE:  
IRB PROTOCOL#: 832826  
PROTOCOL TITLE: Multicomponent Behavioral Sleep Intervention for Insomnia in Older Adults with  
Mild Cognitive Impairment

SPONSOR: NO SPONSOR NUMBER  
REVIEW BOARD: IRB #8

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**IRB SUBMISSION: NOTICE OF APPROVAL**

Dear Dr. Varrasse,

The above referenced protocol was reviewed and approved by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 on 02-Apr-2019. This study has been determined to pose minimal risk to subjects and be eligible for expedited review category(ies) 2,4,6,7.

Consistent with the regulations set forth in 45 CFR 46.109(f), continuing review of this research is not required. IRB approval of this protocol will not expire and continuing review applications should not be submitted. However, you are still required to submit modifications and reportable events to the IRB for review.

The documents included with the application noted below are approved:

-HS ERA Initial submission, confirmation code: cifihdjh, submitted 03/26/2019

**ONGOING REQUIREMENTS:**

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: <http://www.irb.upenn.edu>

\*\*\*This letter constitutes official University of Pennsylvania IRB correspondence. \*\*\*

UNIVERSITY OF PENNSYLVANIA  
RESEARCH SUBJECT  
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

**Protocol Title:**

Multicomponent Behavioral Sleep Intervention for Insomnia  
(MBSI-I) in Older Adults with Mild Cognitive Impairment

**Principal Investigator and Emergency Contact:**

Miranda V. McPhillips, PhD, RN  
3615 Chestnut Street  
Philadelphia, PA 19104  
484-631-5397

**Summary**

You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to better understand ways to improve insomnia symptoms, memory issues and enhance overall quality of life in older adults. If you agree to join the study, you will be asked to complete the following research procedures: complete questionnaires, complete a sleep diary and wear a wrist watch device that measures sleep and activity, have blood drawn, and access modules on a tablet device. There will be 3 in person

visits and phone calls involved in this study. Your participation will last for 4 months. You may not benefit from being in this study, but you might help us better understand ways to improve sleep in the future. The most common risks of participation are feeling anxious or stressed during data collection, wrist watch discomfort, complications related to blood draws or loss of confidentiality. Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

### **Why am I being asked to volunteer?**

You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends and family. If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

### **What is the purpose of the study?**

The purpose of the study is to look at different ways to improve insomnia symptoms, memory issues and enhance overall quality of life. This research will evaluate whether one of two different approaches are helpful in reducing symptoms of insomnia. One approach consists of daytime activity and relaxation therapy at night, and the second approach focuses on education. Previous studies suggest that these approaches can be effective in improving sleep and enhancing quality of life, and we hope to confirm and extend these findings with this research study.

### **Why was I asked to participate in the study?**

You are being asked to join this study because you are community-dwelling older adult who expressed concerns about your sleep and memory.

### **How long will I be in the study?**

The study will take place over a 4 month period. This means for the next 4 months we will ask you to participate in research

related activities. There will be 3 in person visits and we will ask you to do things at home. Each in person session will last approximately 1 hour. We will ask you to wear a wrist watch device and complete a sleep diary for a total of 7 weeks. We will ask you to do access modules on a tablet for a period of one month. You will receive a phone calls throughout the month you are interacting with the tablet device. Calls will last approximately 5-15 minutes. A total of 40 participants will participate in this research study.

### **Where will the study take place?**

Study procedures will take place at Ralston House, located at 3615 Chestnut Street. There is free parking. This location is a University of Pennsylvania Health System site.

### **What will I be asked to do?**

If you express interest in the study, we will go through a screening process with you.

**Screening (Part 1):** We anticipate this process to take about 30 minutes.

- We will assess your cognition via the Montreal Cognitive Assessment (MoCA) form
- We will assess your sleep via a single question asking about insomnia symptoms
- We will go over this consent form in great detail if you meet the requirements for eligibility

**Screening (Part 2):** You will wear a wrist watch device and complete a sleep diary for one week.

- If you choose to be in the study, there will be one more screening process you will go through.

- We will give you instructions for wearing a wrist watch device to measure your activity and sleep and completing a tablet based sleep diary for one week to determine if you meet the requirements for participation in the study.
  - If you do not meet requirements at that point, we will call you and let you know. We will also set up a time that we can get the watch and tablet back from you.
  - If you do meet requirements at that point, you will be asked to meet with a researcher for three in-person visits, wear the wrist watch device and complete the sleep diary for six additional weeks, and receive phone calls from a researcher. You will be randomized to one of two groups (Group A- behavioral sleep intervention or Group B- education only). A detailed breakdown of what you will be asked to do is below.

**Visit 1 (Baseline):** It is estimated that the first research visit will take about 1-1.5 hours.

- You will be asked to complete baseline questionnaires about your demographic information, sleep, health related quality of life, physical activity, cognition, social activity and other health related questions. You will also be asked to give a blood sample. The researcher will then reinforce the instructions for completing the sleep diary and wearing the wrist watch device. You will be sent home with the watch, tablet (includes sleep diary), and instructions. The watch will be worn 24 hours a day and the sleep diary should be completed every morning and evening.
  - You will be instructed how to access Sleep Education information on the tablet and encouraged to view education modules during the next month.
  - **Group A Only:** You will work together with the researcher to develop a personalized meaningful activity plan. You will also be taught and asked to use



Assistive Relaxation Therapy at night. You will be instructed how to access activity modules and the relaxation application on the tablet.

**Phone Calls during Month of Study Involvement:** It is estimated that phone calls will last 5-15 minutes. The researcher will call you once or twice a week to check in and make sure you are not having any problems with the tablet or wrist watch device.

- **Group A Only:** You will work with the research to adjust the activity plan as needed. You will also be encouraged to continue to use the applications on the tablet as instructed.

**Visit 2 (Post-intervention; Week 5):** The second visit will take place at Ralston House. It is estimated that this visit will take one hour. During this visit, you will complete the same questionnaires as Visit 1 and will be asked to give a blood sample. You will also be asked to complete the sleep diary and wear the wrist watch for an additional week. You will have the opportunity to share your experience of participating in the study at this time.

**Visit 3 (12 weeks Post-intervention; Week 16):** The third and final visit will take place at Ralston House. It is estimated that this visit will take one hour. During this visit, you will complete the same questionnaires as Visit 1 and 2 and will be asked to give a blood sample. You will also be asked to complete the sleep diary and wear the wrist watch for one last week. You will have another opportunity to share your experience of participating in the study at this time.

\*If the tablet or watch are lost or stolen, please contact Miranda McPhillips immediately, at 484-631-5397.

## **What are the risks?**

We do not believe there are any major risks associated with this study. The minimal risks are described in detail below.

- 1) You may become anxious, stressed, tired or bored during data collection because of the questions asked, the burden of data collection or for other personal reasons. You do not have to answer any question you do not want to answer. If at any point you want to stop or delay data collection, you can let the researcher know.
- 2) You may experience discomfort from sleeping with the wrist watch device, but that usually subsides after the first night. If you cannot tolerate the watch, you may remove it.
- 3) The drawing of a blood sample is a safe, relatively risk-free procedure. However, there is a small possibility of minor pain, minor bruising, and infection and a small amount of bleeding or fainting.
- 4) Loss of confidentiality is possible, but we will do everything we can to protect your information. We have several safeguards planned to protect against the loss of confidentiality that are described in the confidentiality section below.

## **How will I benefit from the study?**

There may be no benefit to you. However, your participation could help us better understand sleep problems in older adults with memory impairment and determine ways we can improve sleep, which may benefit you indirectly. In the future, this may help other older adults have less difficulty with sleeping.

## **Will I receive the results of research testing?**

We will go over the results of the baseline one week sleep diary and wrist watch data with you. You will have a general idea about your sleep and sleep patterns.

### **What other choices do I have?**

Your alternative to being in the study is to not be in the study.

If you choose not to be in the study, you might consider talking to your provider about other treatment options for your sleep problems.

### **What happens if I do not choose to join the research study?**

You may choose to join the study or you may choose not to join the study. Your participation is voluntary.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your health care team will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

### **When is the study over? Can I leave the study before it ends?**

The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health-you will be informed of the reasons why.

- You have not followed the study instructions
- The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

If you no longer wish to be in the research study, please contact Miranda McPhillips, at 484-631-5397.

### **What information about me may be collected, used or shared with others?**

We plan to look at your medical record if you choose to participate in the study. We will have access to your medical record number and demographic information, such as your name, address, phone number, and date of birth. In addition, we will examine your personal medical history, including medications. Furthermore, we will have results of the questionnaires, blood samples (inflammatory biomarkers), and sleep patterns.

### **Why is my information being used?**

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to by the research team to contact you during the study and to describe your current health status.

### **Who may use and share information about me?**

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team at the University of Pennsylvania (Penn)
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

## **Who might receive my information?**

Your personal health information may be shared with the following people or groups:

- Those working under the direction of the investigator for the study, such as research staff
- The National Institute of Nursing Research
- The institutional review board that approved the study

Once your personal health information is disclosed to others outside these groups, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

## **Will information about this study be available to the public?**

A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This website will not include information that can identify you.

## **How long may the investigators use or disclose my personal health information?**

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the investigators may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

## **Can I change my mind about giving permission for use of my information?**

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

## **What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study. Again, this study is voluntary and if you choose not to give permission to use your health information, there will be no loss of benefits to which you are entitled.

## **What may happen to my information and blood samples collected on this study?**

Your information will be de-identified. De-identified means that all identifiers have been removed. The information and blood samples could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and blood samples only applies to the information and blood samples collected on this study.

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. Most uses of biospecimens or information do not lead to commercial products or to profit for anyone. Whole genome sequencing (i.e., analyzing your entire personal genetic code) will not be conducted on your samples.

## **How will my personal information be protected during the study?**

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. *With your permission, information regarding your sleep habits may be shared with you and/or your primary care provider.*

If you choose to be in the study, you will be assigned a study identification number. The only place where your name and number will be linked is on a password-protected, secure server through the Information Technology (IT) department at the Penn School of Nursing. Your contact information will be stored separately from study data and identifying numbers in a file on a password-protected server. Signed consent forms and other patient-specific information will be kept on the secure server under your unique identification number. Access to these files will be limited to those directly involved in the study. Only de-identified data will be shared with the research team. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Every effort will be made to prevent anyone who is not on the research team from knowing what data were collected from which patient.

### ***Electronic Medical Records and Research Results***

#### **What is an Electronic Medical Record and/or a Clinical Trial Management System?**

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania



research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

### **What happens if I am injured from being in the study?**

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

### **Will I have to pay for anything?**

No. There will be no costs to you for participating in the study.

### **Will I be paid for being in this study?**

You will receive a maximum of \$200 for your participation in the study. You will receive \$50 at the end of Visit 1; \$100 at the end of Visit 2; \$50 at the end of Visit 3. You will only be paid for visits that are completed.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of \$600 in a calendar year.

### **Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?**

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with

the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

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When you sign this form, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

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Printed Name of Participant

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Signature of Participant

Date